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10/808,718

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Gerrit Reinold J. Melles

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BANNER & WITCOFF, LTD.
28 STATE STREET
SUITE 1800
BOSTON, MA 02109-1701

EXAMINER

MILLER, SAMANTHA A

ART UNIT

PAPER NUMBER

3749

MAIL DATE

DELIVERY MODE

01/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/808,718 | Applicant(s) MELLES, GERRIT REINOLD J. | |
| | Examiner SAMANTHA A. MILLER | Art Unit 3749 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt of applicant's amendment filed on 2/5/2009 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-14, and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howorth (3,602,213) in view of van der Waaji (3,893,457).

Howorth teaches:

1. An operation unit (Fig.1) (col.1 l.24), comprising an enclosure at least two side walls (col.1 l.25), a roof element (a1) and a back wall (a3) and a wall (col.1 l.25) the operation unit further including an air flow unit (b1) (col.1 ll.27-29), said air flow unit being provided with means for filtering (d) said air (col.2 ll.3-6 and ll.30-31) (Fig.3), said wall being provided with at least one opening (col.1 ll.44-47) and a cover, covering at least part of said opening (a2) (col.1 ll.40-43), said air flow unit comprising at least one air outlet opening (B) within the enclosed space for directing air from said air flow unit (b1) over said cover (col.2 ll.20-26),

(col.1 ll.44-61) (Fig.1 and 3)

3. The operation unit is at least partly foldable (being made of draped material a2 and lower panels hinged to upper panels) (col.1 ll.48-55).

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4. The sidewalls are foldable over and/or against said flow unit (b) (hooked on rails in ceiling can fold up) (col.2 l.44-47), the back wall preferably being foldable (lower panel hinged and drape material) (col.1 ll.59-61).

5. The cover is substantially made of cloth/sheet, especially a surgery blanket/sheet (col.1 ll.40-43) (Fig.3).

6. The opening is dimensioned such that at least an end of a hospital bed, stretcher or the like can be inserted through said opening under said cover (col.1 ll.45-47).

7. The opening is dimensioned such that an extremity of a person can be inserted at least partly through said opening under said cover (col.1 ll.45-47).

8. The outlet opening (B) extends over at least the width of said at least one opening (Fig.1 shows multiple B extending width wise) (Fig.3 shows size of opening width wise).

9. The outflow direction of said outflow opening is directed downward in a direction away from said wall/drape (a2) (col.2 ll.34-37).

12. At least part of said wall and preferably part of said wall and at least part of side walls and a back wall of said unit are made transparent (col.1 l.25).

14. The air flow unit (b1) is provided near the upper end of said wall and is connected to the air outlet (B) by a first connecting pipe (B duct) and to the air inlet (b) by a second connecting pipe (b duct) (Fig.1), said connecting pipes being provided near either side of said wall, preferably such that said connecting pipes and said air flow unit form part of a frame of said operation unit (Fig.1).

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26. A lower edge of said wall and a floor on which said unit is placed at least one gap is provided (under where the person is inserted), lower than said at least one air inlet opening, for pressure equalization between the inner space of the unit and the environment thereof (Fig.1) (col.1 ll.45-47).

28. The at least one air outlet opening (B) or series of air outlet openings (B) extend over the width of the cover (Fig.1-2).

Regarding Claims 19-25, 27, and 29-32, refer to the rejection of claims 1-12, 14, 26, and 28.

Howorth teaches the invention as discussed above. However, Howorth does not teach a foldable roof element, wheels, or air inlet means provided for retracting air from within said operation unit to said air flow unit.

van der Waaij teaches:

Regarding claims 1 and 19, air inlet means (3) provided for retracting air from within said operation unit (the area formed around the table (11) by the cabinet (1) curtain (15)) to said air flow unit (within 15) (col.2 ll.5-13 and 44-62) (Fig.2), air inlet () means (2) within the enclosed space or operation area for retracting air (from the operation area) to said air flow unit (col.2 ll.51-62) (Fig.1).

4. The sidewalls (15) and roof element (14) are foldable over and/or against said flow unit (1) (col.4 ll.34-43).

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10. The air inlet opening (3) is situated lower than said outflow opening (5) (Fig.1).

11. The openings (3) are provided near the ground for connection of an inner space (1) of said unit and the surrounding (Fig.1).

13. The unit (1) is provided with wheels for easy displacement of said unit (col.3 ll.42-51).

Therefore, it would have been obvious to a person having ordinary skills in the art at the time the invention was made to have modified the operation unit of Howorth in view of the teaching of van der Wajij in order to be adapted the sytem to be placed on extremity of an arbitrary existing operation table and to close the operating space to external air and provide germ free air (van der Waaji, col.3 ll.42-51 and col.4 ll.34-43).

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howorth (3,602,213) in view of van der Waaji (3,893,457) in further view of WIEDNER (5,860,420).

Howorth in view of van der Waaji teaches the invention as discussed above and Howorth further teaches:

15. A method for preparing a person for surgery, in which said person is positioned on a bed, stretcher, chair or the like supporting structure, especially a cloth/sheet,

16. The air is re-circulated through a flow unit filtering said air for sterilization purposes (col.2 ll.31-40).

17. The part of said body is moved through an opening in a wall of an operation unit comprising a wall and an air flow unit, said air flow unit being provided with means for filtering said air, said wall being provided with at least one opening and a cover, covering at least part of said opening, said air flow unit comprising at least one air outlet opening for directing air from said air flow unit over said cover,

18. A method for performing surgery on a person, in which said person is positioned on a bed, stretcher, chair or the like supporting structure, whereby part of the body of said person on which surgery is to be performed is moved through an opening under a cover, especially a cloth/sheet,

van der Waaij further teaches:

17. air inlet (3) means preferably being provided for retracting air to said air flow unit (col.2 ll.51-62) (Fig.1).

Howorth in view of van der Waaji teaches the invention as discussed above. However, Howorth in view of van der Waaji does not teach an opening being provided in said cloth disclosing an operation area.

WIEDNER teaches:

15. whereby part of the body of said person on which surgery is to be performed is moved through an opening under a cover (col.8 ll.56-62), an opening being provided

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in said cloth disclosing an operation area, a flow of substantially sterile air being guided over said cover and at least said operating area (col.8 ll.56-62) (Fig.3).

18. an opening being provided in said cloth disclosing an operation area, a flow of substantially sterile air being guided over said cover and at least said operating area (col.2 ll.31-40) (Fig.3).

Therefore, it would have been obvious to a person having ordinary skills in the art at the time the invention was made to have modified the operation unit of Howorth in view of van der Waaij in further view of WIEDNER in order to retain sterile and clean conditions at an operation site (col.1 ll.9-10).

Response to Arguments

Applicant's arguments filed 10/27/2009 have been fully considered but they are not persuasive.

Applicant contends that Howorth teaches away from van der Waaij retracting air from within said enclosure. Howorth does not teach a return duct thus does not teach retracting the air from the enclosure, however Howorth does not teach you can not have a return duct. Van der Waaij teaches a operation enclosure that retracts the inlet air it would have been obvious to a person having ordinary skills in the art at the time the invention was made to have modified the operation unit of Howorth in view of the teaching of van der Wajij in order to be adapted to be placed at on extremity of an arbitrary existing operation table and to close the operating space to external air and provide germ free air (van der Waaij, col.3 ll.42-51 and col.4 ll.34-43).

Applicant contends that Howorth does not teach a roof, however claims are afforded the broadest reasonable interpretation and as applicant has pointed out Howorth teaches a ceiling of the operation enclosure. The ceiling is clearly the roof (a1) of the operation enclosure (shown in Fig.3 as surrounding the outlet structure B and b1).

Applicant contends that Howorth does not teach an outlet or inlet within the enclosure. Regarding claim 1 in the rejection above Howorth teaches the outlet (B) clearly in the operation enclosure being within the ceiling shown in Fig.3.

Applicant contends that Howorth does not teach the outflow direction directed downward away from said wall, an air inlet opening is situated lower than said outflow opening, or a cloth disclosing an operation area. However, claims are afforded their broadest reasonable interpretation.

In this instant application, the outflow direction of said outflow opening is directed downward in a direction away from said wall/drape, the air inlet opening (around operating table) is situated lower than said outflow opening, and an opening being provided in said cloth disclosing an operation area. It should be apparent that Howorth teaches airflow in a downward direction and parallel to the wall (a2) not towards the wall thus driving the airflow away from the wall (col.2 ll.34-37). Howorth also teaches two air inlet openings and the air inlet opening (around operating table) is situated lower than said outflow opening (B) (Fig.3). The cover Howorth teaches (col.1 ll.43-45) has an opening (around operating table) where the patient is placed for the operation (col.1 ll.43-45, col.2 ll.31-40) (Fig.3).

Applicant contends that Waaji does not teach retracting air from within said operation unit because the retracted air is from outside the operation unit. However, claims are afforded the broadest reasonable interpretation. In this case, the operation unit taught in Waaji is the area formed around the table (11) by the cabinet (1) curtain (15). Waaji then retracts the air from within said operation unit being air from the operation area, (col.2 ll.51-62) (Fig.1).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the operation unit of Howorth to include the retracting air from the bottom of the unit as taught in Waaji in order to be adapted to be placed at on extremity of an arbitrary existing operation table and to close the operating space to external air and provide germ free air (van der Waaij, col.3 ll.42-51 and col.4 ll.34-43).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR '1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS

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from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha A. Miller whose telephone number is 571-272-9967. The examiner can normally be reached on Monday - Thursday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve McAllister can be reached on 571-272-6785. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Samantha Miller

Examiner

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1/16/2010

/Steven B. McAllister/

Supervisory Patent Examiner, Art Unit 3749